

Clinical Study Results



Research Sponsor: Eisai Korea Inc.
Drug Studied: Perampanel, also called E2007
Short Study Title: A study of a medicine called perampanel in people with epilepsy

Thank you

You or your child took part in this clinical study for the study medicine perampanel, also called E2007. Everyone who participated helped researchers learn more about perampanel and how it may help people with epilepsy.

Epilepsy is a brain condition that causes repeated seizures, which can affect movement, sensations, behavior, or awareness.

Eisai, a Japanese pharmaceutical company that was the sponsor of this study, thanks you for your help. Eisai is committed to improving health through continuing research in areas of unmet need and sharing study results with participants.

Eisai has prepared this summary of the study and its results with a medical and regulatory writing organization called Certara Synchrogenix.

If you or your child participated in this study and have questions about the results, please speak with the doctor or staff at your study site.

What has happened since the study started?

The study included 125 participants from 10 sites in South Korea. It started in October 2022 and ended in January 2025.

Out of 125 participants included in the study, 120 took at least 1 dose of perampanel.

The sponsor of the study reviewed the data collected and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers were looking for a different way to treat people with epilepsy who have focal onset seizures. Standard treatment for epilepsy includes medicines to help prevent or reduce symptoms.

Focal onset seizures (or **FOS**) are seizures that start in one area of the brain that may cause symptoms such as unusual movements, changes in feelings or sensations, staring, confusion, or loss of awareness.

The researchers in this study wanted to find out if perampanel helps people with epilepsy experience fewer seizures. They also wanted to find out if people had any medical problems during the study.

The main questions the researchers wanted to answer in this study were:

- Can perampanel reduce the number of seizures?
- What adverse events did participants receiving perampanel have? An adverse event is a medical problem that may or may not be caused by the study drug.

It is important to know that this study was designed to get accurate answers to the questions listed above. There were other questions the researchers wanted to answer to learn more about how perampanel works, but these were not the main questions the study was designed to answer.

What kind of study was this?

To answer main questions above, researchers asked for the help of participants who were between 4 and 82 years old. Of these participants, 55% were male and 45% were female.

All of the participants in this study had FOS because of epilepsy.

This study was “open-label.” This means that the participants, the study doctors and staff, and the sponsor knew what dose of perampanel participants took.

The **Treatment Phase** was divided into 2 parts:

- **Part 1:** Researchers tried to find out the highest dose of perampanel that participants could tolerate. Participants took perampanel between 2 milligrams (or mg) and 8 mg tablets once daily for up to 2 months (8 weeks).
- **Part 2:** Participants who did not have any safety concerns in Part 1 entered Part 2. Participants took perampanel tablets at the dose that they could tolerate once daily for up to 5 and a half months (24 weeks).

Eligible participants who completed the Treatment Phase were given a chance to continue taking treatment in an **Extension Phase**. Using the dose in Part 2, participants took perampanel tablets once daily for up to 5 and a half months (24 weeks).

The figure below shows how treatment was given in the study.



120 participants
took at least 1 dose
of **perampanel**



Perampanel was taken
as tablets once daily



Participants took
perampanel for up to
8 or 13 months

What happened during the study?

Before the study started, the doctors did a full check-up to make sure each participant could join the study.

The doctors also:

- Confirmed participants whether they have FOS because of epilepsy
- Took blood samples
- Asked participants about their seizure information

During the treatment period, participants took their assigned doses of perampanel once daily for about 8 months (up to Treatment Phase) or 13 months (up to Extension Phase).

Throughout the study, the doctors:

- Collected information about participants' seizures
- Took blood samples
- Asked about medical problems participants might have and medicines participants were taking

About a month (4 weeks) after their last dose, all participants visited the site for a final check-up.

During this visit, the doctors also:

- Took blood samples
- Asked about medical problems participants might have and medicines participants were taking

Participants who stopped taking perampanel early visited the site twice – within 7 days and a month (4 weeks) after taking the last dose of perampanel.

The figure below shows how the study was done.

How did this study work?

Before the treatment period

The study doctors or staff:

- Checked each participant's health to make sure they could join the study
- Confirmed that participants have FOS because of epilepsy
- Asked about participants' seizure information

During the treatment period

All participants took their assigned dose of perampanel tablets once daily.

The study doctors or staff:

- Collected seizure information
- Asked about medical problems participants experienced and other medicines that participants took

After the treatment period

Participants who completed treatment returned to study sites **a month** after their last dose of perampanel.

During this visit, the study doctors or staff checked participants' health and asked about medical problems they experienced and other medicines they took.

What were the results of the study?

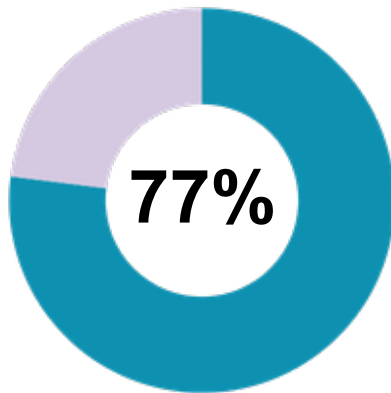
This is a summary of the main results of this study. Each participant's individual results were different and unique to them. Individual results are not given separately in this summary, but all participants' results are summarized together here. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

Researchers look at the results of many studies to decide which treatment options may work best and are well tolerated by patients. Other studies may provide new information or different results. Always talk to a doctor before making any treatment decisions.

Can perampanel reduce the number of seizures?

To answer this question, study doctors used the participants' diaries to count the number of participants who never had seizures during Part 2 of the Treatment Phase. Results in this section were from participants who took at least 1 dose of perampanel and completed at least 1 study assessment after taking it.

The chart below shows the percentage of participants who never had seizures during Part 2 of the Treatment Phase.



A total **51** out of **66** participants did not have seizures during Part 2 of the Treatment Phase.

What medical problems did participants have?

Medical problems that happen to participants in clinical studies are called “adverse events”. If the study doctors thought an adverse event was caused by the study drug, it is called an “adverse reaction”. Adverse events or reactions are considered “serious” if the participant needs to be admitted to a hospital, if they are life-threatening, or if they cause lasting health problems.

This section is a summary of the adverse events and adverse reactions that happened during this study. The websites listed at the end of this summary may have more information about these. A lot of research is needed to know whether a drug may cause a particular medical problem.

How many participants had adverse events?

The table below shows how many participants had adverse events in this study.

Adverse Events in This Study

	Treatment Phase	Extension Phase
	Out of 240 participants in Total	Out of 64 participants Total
How many participants had adverse events?	105 (44%)	21 (33%)
How many participants had serious adverse events?	5 (2%)	3 (5%)
How many participants stopped receiving the perampanel because of adverse events?	14 (6%)	0

What were the most common serious adverse events?

There were no common serious adverse events in the study. All serious adverse events were reported once throughout the study.

No participants died during the study.

What were the most common adverse events?

The most common adverse events were:

- Dizziness
- Headache
- Nose and throat infection (upper respiratory tract infection)

The table below shows the adverse events that happened in 3 participants or more in any part of the study. There were other adverse events, but these happened in fewer participants.

Most Common Adverse Events in This Study

	Treatment Phase	Extension Phase
	Out of 240 participants in Total	Out of 64 participants Total
Dizziness	58 (24%)	1 (2%)
Headache	13 (5%)	1 (2%)
Nose and throat infection (upper respiratory tract infection)	7 (3%)	3 (5%)
Infection of the airways (respiratory tract infection)	5 (2%)	3 (5%)
Sleepiness (somnolence)	7 (3%)	0
Feeling sick (nausea)	4 (2%)	2 (3%)
Flu (influenza)	2 (1%)	3 (5%)
Reduced sensation to touch, pain, and temperature (hypoesthesia)	4 (2%)	0
Inflammation of the sinuses (sinusitis)	4 (2%)	0
Chest discomfort	4 (2%)	0

How many participants had adverse reactions?

Adverse reactions are medical problems that the study doctors thought were caused by the study drug. An adverse reaction is called “serious” when it is life-threatening, causes lasting problems, or the participant needs to be admitted to a hospital. This section is a summary of the adverse reactions that happened during this study.

The table below shows how many participants had adverse reactions.

Adverse Reactions in This Study

	Treatment Phase	Extension Phase
	Out of 240 participants in Total	Out of 64 participants Total
How many participants had adverse reactions?	67 (28%)	2 (3%)

What were the most common adverse reactions?

The most common adverse reaction in the study was **dizziness** – reported by a total of 54 participants. There were other adverse reactions, but these happened in fewer participants.

How has this study helped patients and researchers?

In this study, researchers learned more about how perampanel may have helped people with epilepsy.

Researchers look at the results of many studies to decide which treatment options may work best and are well tolerated. This summary shows only the main results from this one study. Other studies may provide new information or different results.

No further clinical studies with perampanel are planned.

Where can I learn more about the study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it can also be found here:

- <http://www.clinicalstudies.gov> - Once you are on the website, type **NCT05533814** into the search box and click “**Search**”.

Full study title: A multi-center, open-label, prospective clinical study, including the Extension Phase, to assess the efficacy and safety of perampanel monotherapy in subjects who have focal onset seizures (FOS) with or without untreated focal to bilateral tonic-clonic seizures

Protocol number: E2007-M082-606

Eisai, the sponsor of this study, has headquarters in Tokyo, Japan, and regional headquarters in Nutley, New Jersey, USA and Hatfield, Hertfordshire, UK. The phone numbers for general information are +1-888-274-2378 (USA) and +44-845-676-1400 (UK).

Thank you

Eisai would like to thank you for your time and interest in participating in this clinical study. Your participation has provided a valuable contribution to research and improvement in health care.



Eisai Co., Ltd. is a global research and development-based pharmaceutical company headquartered in Japan. We define our corporate mission as “to give first thought to patients and the people in the daily living domain, and increase the benefits that health care provides to them as well as meet diverse healthcare needs worldwide”, which we call our human health care (*hhc*) philosophy. With over 10,000 employees working across our global network of R&D facilities, manufacturing sites, and marketing subsidiaries, we strive to realize our *hhc* philosophy by delivering innovative products in multiple therapeutic areas with high unmet medical needs, including oncology and neurology. For more information, please visit <http://www.eisai.com>.